Public Chapter 527

HOUSE BILL NO. 1124

By Representatives Chumney, Eckles

Substituted for: Senate Bill No. 979

By Senators Ford, Person

AN ACT to amend Tennessee Code Annotated, Title 4; Title 56; Title 68 and Title 71, relative to health care.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 71, Chapter 1, is amended by adding Sections 2 through 8 of this act as a new part:

SECTION 2. This act shall be known and may be cited as the "TennCare Drug Formulary Accountability Act".

SECTION 3. The Bureau of TennCare (hereinafter referred to as the Bureau) shall have conducted, by an entity other than the Department of Health, a clinical analysis of the drug formulary of each managed care organization (hereinafter referred to as MCO) and each behavioral health organization (hereinafter referred to as BHO) which has a TennCare contract, to assure that the formulary of each MCO and/or BHO is therapeutically sound. Such study shall:

(1) Provide for input by a medical and pharmaceutical advisory committee comprised of persons not employed by the State of Tennessee, MCOs, BHOs or pharmacy benefits managers (hereinafter referred to as PBMs) responsible for the current formularies. Participants shall have no business related conflict of interest. Participation by TennCare health practitioners shall not constitute a conflict of interest. Nothing contained in this section shall be construed or interpreted to prohibit the inclusion of persons employed by State Universities from participation on the committee;

(2) Be completed no later than December 15, 1997; and

(3) Be reported, upon completion, to the legislative TennCare Oversight Committee (hereinafter referred to as the Oversight Committee).

SECTION 4. The Bureau, with input from the TennCare Pharmaceutical Care Advisory Board, created pursuant to Section 5 of this act, shall develop a process for MCO and BHO formulary development and management. If a PBM is utilized, the MCO and/or BHO shall require that the PBM utilize the same process for development and management of the formulary. The process developed pursuant to this section shall meet the following requirements:

(1) There shall be an advisory committee for each MCO and or BHO whose purpose shall be to provide input into the development and management

of a drug formulary used by the MCO, BHO OR PBM. The MCO and/or BHO shall retain initial decision making authority with respect to issues affecting the MCO's or BHO's formulary. Provided, however, the Bureau of TennCare shall retain final decision making authority with respect to the formulary of each MCO and/or BHO and may require additions or changes in the formulary as the Bureau deems appropriate and necessary.

(A) Every MCO and BHO shall have a mechanism in place to assure that practicing TennCare prescribers (including physician primary care providers, physician specialists, non-physician primary care practitioners and non-physician prescribers), and pharmacists have input into the development and updating of the formulary through the advisory committee.

(B) The advisory committee shall consist of individuals who are not owners of the MCO, BHO or PBM and who have no business related conflict of interest.

(C) A current list of advisory committee members shall be on file with the Bureau and the Board of Pharmacy. The Bureau of TennCare may require changes in the membership of the advisory committee as necessary to promote effectiveness of the advisory committee.

(2) The process shall delineate the factors that should be considered and the factors, if any, that may not be considered in decisions affecting the formulary.

(3) Describe the minimum frequency for formulary revisions;

(4) Describe the minimum frequency for disclosure of formulary information to TennCare physicians and other prescribers.

(5) Describe required data collection, verification, and reporting by MCOs and BHOs to the Bureau;

(6) Each MCO shall have the advisory committee required pursuant to this section established no later than December 15, 1997; and

(7) If the Bureau of TennCare determines that an MCO or BHO is not in compliance with the designated process, the Bureau shall require the MCO and BHO to allow prescribers to prescribe using an open formulary until such time as the MCO or BHO can demonstrate to the satisfaction of the Bureau of TennCare that the MCO or BHO has achieved compliance. The Bureau of TennCare shall provide reasonable advance notice to the MCO or BHO of any directive by the Bureau of TennCare to operate an open formulary pursuant to the provisions of this section.

SECTION 5. The TennCare Pharmaceutical Care Advisory Board shall be a statewide independent board, appointed by the Commissioner of Health.

(a) Membership shall include:

(1) Two (2) practicing TennCare pharmacists who practice at pharmacy practice sites as defined by the Tennessee Board of Pharmacy, selected from a list submitted by the decision making board of the Tennessee Pharmacists Association.

(2) Five (5) individuals licensed and actively engaged in the practice of medicine in Tennessee under Title 63, Chapter 6, and who are TennCare practitioners, selected from a list submitted by the Tennessee Medical Association. At least one (1) of these individuals shall be a primary care physician. At least one (1) of these individuals shall be actively engaged in the provision of mental health and/or substance abuse services. At least one (1) of these individuals shall be a pediatrician.

(3) One (1) individual with expertise in therapeutic pharmacology who is neither a practicing physician nor a practicing pharmacist, selected from a list submitted by the Pharmaceutical and Research Manufacturers of America. This individual shall be a resident of the State of Tennessee.

(4) One (1) individual with expertise in managed health care selected from a list submitted by the Tennessee Association of HMOs.

(b) Members shall not be government employees and shall have no business related conflict of interest. Participation by TennCare health practitioners shall not constitute a conflict of interest.

(c) The Commissioner of Health may reject any or all recommendations, in which case the nominating process shall continue until appointments are finalized by the Commissioner.

(d) The initial list of nominees shall be submitted to the Commissioner of Health by September 1, 1997; final appointments shall be no later than October 1, 1997.

(e) Members shall be appointed for three (3) year terms, and initial appointments shall be staggered.

(f) The Commissioner of Health in making appointments to the Board shall do so with a conscious intention of selecting a body that reflects a diverse mixture with respect to race and gender. If the nominees of any group do not reflect the diversity of the State's population the Commissioner may reject the entire list of such group and require the group to resubmit its list of nominees.

(g) In addition to providing assistance to the Bureau of TennCare in developing a process for MCO and BHO formulary development and management as described in Section 4, the TennCare Pharmaceutical Care Advisory Board shall provide assistance to the Bureau of TennCare in the following areas:

(1) solicitation of input from patients and other parties affected by MCO and BHO decisions;

(2) evaluation of new drugs and biologics;

(3) restrictions on access to medications; and

(4) override of access restrictions.

(h) The purpose of the Advisory Board is to provide advice and input to the Bureau of TennCare with respect to drug formulary issues. The Bureau of TennCare shall retain decision making authority with respect to all issues affecting the TennCare program.

SECTION 6. The Bureau shall require any MCO or BHO utilizing a restricted formulary to include in its prior approval and medical necessity procedures the following:

(a) The initial denial of a prescriber's request for coverage of a drug may be made by a physician reviewer or a non-physician health care professional operating in accordance with a physician approved protocol.

(b) The prescriber must have the opportunity to appeal an initial denial by a faxed request for appeal, stating the reason(s) for requesting the drug and attaching any information the prescriber wishes to have considered.

SECTION 7. The Bureau shall review the pharmacy benefits information distributed by MCOs and BHOs to enrollees. The MCOs and BHOs shall inform enrollees at the next printing of the member handbook that prescription drugs are available and shall include each of the following items:

(1) Limitations - Unless an open formulary is used, the information shall mention that the formulary used may require prior authorization or proof of medical necessity before a patient can obtain certain medications, even if the medications are prescribed by the patient's physician.

(2) Exclusions - The information shall mention examples of drugs that are excluded (e.g. over-the-counter drugs and drugs for cosmetic purposes).

(3) Deductibles and co-payments, if applicable should be mentioned in the pharmacy benefits section.

(4) Special Fees - The notice should inform enrollees they may be required to pay for medications that are not approved by the MCO or BHO.

SECTION 8. This act shall take effect upon becoming a law, the public welfare requiring it.